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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,376	05/30/2001	Jeffrey P. Bodner	279.368US1	7232

21186 7590 05/21/2003

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,376

Applicant(s)

BODNER, JEFFREY P.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment filed 4/7/03

1. The Applicant's arguments with respect to claims 1-29 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment of the claims.

Claim Rejections - 35 USC § 103

2. Claim 1-4, 6-20, 22, 24, 25, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al. (US 5545201) in view of Doan (US 5425755).

Helland et al. disclose implantable bipolar pacing lead with two coiled conductors (160, 162) and an electrode assembly with an extendable electrode (142) (figure 6; col. 2 @ 32-54; col. 3 @ 13-17; col. 4 @ 55 – col. 5 @ 15).

As to claims 1, 2, 7 and 11, the first and/ or second conductors are a wire or a coiled conductor (col. 3 @ 13-17).

As related to claims 3, 4, 11, 19 and 24, the insulation sheath (164) is read as a sleeve or tube (figure 6).

As related to claims 1, 8, 11, 14, 18 and 25, the electrode assembly contains a fixed or movable helix electrode (144) coupled to the second conductor. The electrode is rotated and positioned using a stylet and the outer sheath (col. 2 @ 49-53 and 58-60; col. 4 @ 58-63; col. 5 @ 9-13).

As discussed in the previous five paragraphs of this action, Helland et al. discloses the claimed invention except for the conductors having one or more filars (claims 1, 11), the filars having an outer surface surrounded by an insulative coating, creating a redundant insulation

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(claims 1, 6, 11, 13, 18, 20, 24, 28 and 29), the insulative coating being ETFE (claim 10, 15-17), and the tubing being polyurethane (claim 22).

As to the conductors having one or more filars, Doan teaches lead conductors using a multi-filar construction for the purpose of providing a proven conductor for implant applications that enables the transfer of electrical signals. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used multi-filar conductors in the Helland et al. system in order to provide a material of construction for the conductor with known performance relative to the associated insulation, so the torque characteristics of the lead components can be considered and optimized (col. 2 @ 17-26).

As to the filars having an outer surface surrounded by an insulative coating, the insulative coating being ETFE, Doan teaches the lead insertion using filars having an outer surface coated with a biocompatible TEFLON™ coating, such as ETFE, for the purpose of minimizing the frictional resistance between the coated coil and the surrounding insulation. ETFE is a material well known in the conductor art for use as a conductor insulator (US 5845396 to Altman et al. – col. 7 @ 11-16). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the filars having an outer surface surrounded by an insulative coating of ETFE in the Doan system in order to reduce the coefficient of friction between the outer coil and outer insulation so the lead has increased flexibility facilitating the positioning and fixation in the heart, and so the torque associated with the inner coil and tubing is reduced when the helix electrode is extended or retracted to minimize damage to the lead (abstract; col. 2 @ 17-26; col. 4 @ 5-10).

As to the tubing being polyurethane, Doan teaches lead construction using polyurethane tubing for the purpose of minimizing the frictional resistance. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a polyurethane tube in the Helland et al. system in order to minimize the torque transfer between the coated coils and insulation so the lead can be placed in the heart and the electrode secured with optimum ease and minimum stress and strain on the lead (col. 2 @ 17-26).

3. Claims 5, 21, 23, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland et al. (US 5545201) in view of Doan (us 5425755) and further in view of Altman et al. (US5845396). As discussed in paragraph 2 of this action, modified Helland et al. disclose the claimed invention except for the insulation being a non-silicon/ polyimide material (claims 5 and 21), the insulation being heat-shrunk PTFE / ETFE material (claims 23 and 27), and the insulative coating being polyurethane (claim 26).

As to claims 5 and 21, Altman et al. teach signal conduction using a lead with polyimide coated conductors for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

As to claims 23 and 27, Altman et al. teach a lead with heat-shrunk PTFE / ETFE insulated conductors for the purpose of reinforcing the lead to resist the residual stresses in the coating. It would have been obvious to one having ordinary skill in the art at the time of the

invention to have used a heat-shrunk PTFE/ ETFE insulated conductors in the modified Helland et al. system in order to have the design flexibility to create leads that have more conductors and smaller diameters than traditional leads (col. 2 @ 59-64; col. 3 @ 26-42; col. 4 @ 25-32; col. 7 @ 11-16).

As to claim 26, Altman et al. teach signal conduction using a conductor with a polyurethane coating for the purpose of isolating the conductors so noise and artifacts do not degrade the quality of the electrical signals. It would be an obvious design choice to fashion the insulation by substituting one known lead insulating material for another as a mere substitution of known functional equivalents in order to effectively insulate the conductors so electrical signals associated with the heart can be accurately sensed and delivered (col. 1 @ 6-10; col. 2 @ 34-36).

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). The Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
5-12-03

Angela D. Sykes

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